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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/068,212

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Neal E. Fearnot

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8926

7590

05/24/2007

Kenneth A. Gandy
Woodard, Emhardt, Naughton, Moriarty & McNett
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/068,212

Applicant(s)

FEARNOT ET AL.

Examiner

Cheryl Miller

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3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

New art was found and applied in the present office action. The present office action is Non-Final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 16-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "one of said apertures" in line 3. There is insufficient antecedent basis for this limitation in the claim. Only one aperture has been claimed in independent claim 1.

Claim 16 recites, "the lumen includes a first extension adjacent to a first aperture". It is unclear how a lumen may include structural components, when a lumen is just space. This limitation is indefinite. Claims 17-25 depend upon claim 16 and inherit all problems associated with the claim.

Claim 22 is missing a period at the end of the claim.

Claim 23 recites the limitation "the second biocompatible material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Claim 26 recites the limitation "the collagenous biomaterial" in line 9. There is insufficient antecedent basis for this limitation in the claim. Claims 27-29 depend upon claim 26 and inherit all problems associated with the claim.

Claim 27 recites the limitation "the tube" in line 2. There is insufficient antecedent basis for this limitation in the claim. Although a tube is mentioned in the preamble, it is mentioned in the intended use format, a tube has not yet been positively claimed as being formed.

Claim 30 recites, "the lumen and having a plurality of extensions and apertures extending therethrough". This is indefinite, since a lumen is space and it is unclear how the lumen may have extensions and apertures therethrough.

Claim 31 recites the limitation "the underlying material" in line 6. There is insufficient antecedent basis for this limitation in the claim. Claims 32-41 depend upon claim 31 and inherit all problems associated with the claim.

Claim 33 recites the limitation "said seams" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites, "said lumen having a discontinuous, sealed seam". This is indefinite, since a lumen is space and it is unclear how the lumen may have a seam. Claims 43-45 depend upon claim 42 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 22, and 25 are rejected under U.S.C. 102(b) as being anticipated by Ahn (US 5,527,355). Ahn discloses a medical device comprising a compliant sealed tube having a lumen (see figs.7, 9), the lumen having a first extension (end of strap band 46, 66) adjacent an aperture (opening in buckle 64, 44, of fig.7, 9), wherein the extension (end of band 46, 66) extends through the aperture (opening in buckle) to overlie an underlying layer of material (remainder of strap/band, see figs), wherein the layers are bonded together (Velcro or adhesive, col.4, lines 18-23). Ahn discloses a second material (Velcro seen in figs), wherein the extension includes a retainer (the Velcro may be considered a retainer, as could an adhesive).

Claims 16, 22, and 25 are rejected under U.S.C. 102(e) as being anticipated by Myers (US 6,949,119 B2). Myers discloses a medical device (81; fig.8) comprising a compliant sealed tube having a lumen (see fig.8), the lumen having a first extension (inverted portion of sleeve, 83) adjacent an aperture (opening of lumen 87), wherein the extension (inverted sleeve portion 83) extends through the aperture (opening in lumen 87) to overlie an underlying layer of material (remainder of sleeve 85), wherein the layers are bonded together (col.8, lines 1-7), wherein the extension (83) includes a retainer (stent 10).

Claims 16, 22, and 25 are rejected under U.S.C. 102(e) as being anticipated by Wallace et al. (US 6,669,719 B1). Wallace discloses a medical device (fig.56) comprising a compliant sealed tube (stent 1) having a lumen (see fig.56), the lumen having a first extension (extension may be considered either the inner edge of stent OR the adhesive plug) adjacent an aperture

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(aperture may be considered opening of lumen OR openings in stent 174), wherein the extension (inner edge of stent 1 OR plugs) extends through the aperture (opening in lumen or openings 174) to overlie an underlying layer of material (other layers of stent 1), wherein the layers are bonded together (by adhesive bonding plugs; col.24, lines 52-62), wherein the extension (inner edge of stent 1 or plugs) includes a retainer (stent adhesive plugs retain layers together).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 31, 42, 44, and 45 are rejected under U.S.C. 103(a) as being unpatentable over Myers (US 6,949,119 B2). Myers discloses a medical device substantially as claimed, see above, having a non-continuous seam (bonded intermittently around stent struts), however does not disclose the medical device to be formed of collagen submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a submucosal collagen implant since this would involve a mere obvious change of material. *In re Leshin* 227 F.2d 197, 125, USPQ 416 (CCPA 1960).

Claims 1-13 are rejected under U.S.C. 103(a) as being unpatentable over Bose et al. (US 6,666,882 B1). Bose discloses a medical device (700; fig.7) comprising a first compliant material (sleeve 700) having an aperture (slits seen in fig.7) extending therethrough, the material also having an extension (tabs 701) having a width greater than the aperture (fig.7), foldable for receipt therethrough (foldable materials are disclosed; flexible, compliant, soft, examples,

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Dacron, PTFE, etc; col.16, lines 58-68; col.17, lines 1-5, 17-20; col.19, lines 1-5). Bose discloses the medical implant (700) substantially as claimed, made of a flexible foldable material, however does not specifically disclose the implant to be made of collagen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a collagen implant since this would involve a mere obvious change of material. . *In re Leshin* 227 F.2d 197, 125, USPQ 416 (CCPA 1960).

Bose discloses a plurality of apertures (slits) in the form of slits (fig.7) and plurality of extensions (701) generally rectangular in shape, the extensions including a retainer (wider edge preventing from pulling backward, thus retaining). Bose discloses a second material (drug, col.17, lines 25-27).

Claims 17, 19, 31-35, and 39-45 are rejected under U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,669,719 B2). Wallace discloses a medical device substantially as claimed (see above). Wallace discloses the device free from a continuous seam edge (the layers are sealed intermittently by plugs along the edge, creating a plurality of sealed seam longitudinal lines). Wallace discloses the seam to be formed of edge portions (perimeter of apertures 174) and non-edge portions (area inbetween plugs). Wallace discloses a medical device substantially as claimed, see above, having a non-continuous seam (bonded intermittently around stent struts), however does not disclose the medical device to be formed of collagen submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a submucosal collagen implant since this would involve a mere obvious change of material. *In re Leshin* 227 F.2d 197, 125, USPQ 416 (CCPA 1960).

Allowable Subject Matter

Claims 14,15,18,20,21,23,24, 26-30, and 36-38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

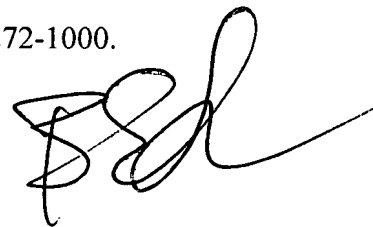
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER